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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,556	03/24/2004	Charles A. Kunsch	PB248D1	2889

22195 7590 10/13/2006

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EXAMINER
DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/807,556	KUNSCH ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Prior to setting forth the restriction requirement, it is noted out that the claims recite improper Markush Groups. M.P.E.P. 803.02 states that: Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, *unless the subject matter in a claim lacks unity of invention* [emphasis added], *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility." In the instant case, the method and products rely upon polypeptides, polynucleotides and antibodies which differ in both structure and modes of action (function) to such an extent and require non-coextensive searches to such an extent that they are considered to lack a substantial structural feature disclosed as being essential to the disclosed utility.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 6 and 15 drawn to multiply distinct polynucleotides encoding multiply distinct polypeptides with open reading frames or variant, vectors and methods of producing the protein, classified in class 536, subclass 23.7.

II. Claims 5 and 8-13 drawn to a multiply distinct polypeptide open reading frames and epitopes as set forth in Tables 2, 3 and 4, classified in class 530, subclass 350.

III. Claim 7 drawn to a multiply distinct antibodies that bind multiply distinct polypeptide open reading frames as set forth in Tables 2 and 3, polypeptide, classified in class 530, subclass 387.1.

IV. Claim 14 drawn to methods of using the multiply distinct polypeptide open reading frames and epitopes as set forth in Tables 2, 3 and 4 classified in class 424, subclass 183.1.

Groups I, II and III are drawn to different products. The claims of Group I are drawn to a nucleic acid fragment of one of SEQ ID NOS: 1-5,191 depicted in Tables 2 and 3; that of Group II are drawn to an isolated polypeptide encoded by SEQ ID NOS:1-5,191 as depicted in Tables 2, 3 or fragments thereof (Table 4); and that of Group III are drawn to antibodies that bind an isolated polypeptide encoded by SEQ ID NOS:1-5,191 as depicted in Tables 2 and 3.

The Groups are independent and distinct from each of the other Groups because the DNAs, vectors, and host cells and methods are materially different from and are therefore independent and distinct from the polypeptides and antibodies. Additionally, the DNAs and vectors are not needed to produce the polypeptides, because the polypeptides may be purified from naturally occurring sources or may be synthesized chemically. Neither is any of the polypeptides claimed needed to produce any of the DNAs or vectors. The DNA and vectors and methods are not necessary for the production of any of the antibodies, nor are the antibodies needed to make any of the DNAs and vectors, transgenic organisms or to practice any of the methods. The polypeptides are distinct from the antibodies because they are functionally and chemically distinct. The proteins perform a cellular function whereas the antibodies mediate immune responses and bind the proteins. Each of the polynucleotides encoding polypeptides, polypeptides and antibodies of the individual Groups are distinct, each from the other, because they are chemically and functionally distinct entities and a lack a substantial structural feature in common disclosed as being essential to the disclosed utility. Each of the antibodies are distinct each from the other because they are chemically and functionally distinct entities which bind separate distinct polypeptide sequences and the search for an antibody which

binds one specific sequence would not encompass the others. The search for one would not encompass a search for any other particular nucleotide or polypeptide sequence. The inventions can be shown to be distinct because they are made by different methods and because they are physically and functionally distinct chemical entities.

Groups I-III, are drawn to multiple individual chemically and functionally distinct polynucleotides, polypeptides and antibodies as set forth above. Should applicant elect any of Groups I-III applicant should elect a ***single*** open reading frame, a ***single*** polypeptide or ***single*** antibody which binds a single polypeptide for prosecution on the merits will be restricted.

Inventions of polynucleotides of Group I, SEQ ID NOS: 1 to 5,191 as depicted in Tables 2 and 3 are drawn to polynucleotides are related as products which share an alleged common utility of detection *S. aureus* but the common utility is not linked to a substantial structural feature. The products in this relationship are distinct if either or both of the following can be shown: (1) that the products encompass embodiments that are not required to perform the common utility or (2) that the products as claimed can be used to perform another utility. In this case, the polynucleotides can be used to produce the polypeptides *in vitro* or as administered as a vaccine.

Inventions of the polypeptides of SEQ ID NOS: 5,192 to 5,255 (claim 10) or fragments thereof depicted in Tables 2 and 3 (i.e. claim 4) are drawn to polynucleotides are related as products which share an alleged common utility of detection *S. aureus* but the common utility is not linked to a substantial structural feature. The products in this relationship are distinct if either or both of the following can be shown: (1) that the products encompass embodiments that are not required to perform the common utility or

(2) that the products as claimed can be used to perform another utility. In this case, the polynucleotides can be used to produce an antibody or administered as a vaccine.

Inventions of the antibodies that bind polypeptides encoded by fragments of the S. aurues genome of SEQ ID NO:1-5,191 as depicted in Tables 2 and 3 are drawn to antibodies are related as products which share an alleged common utility of detection *S. aureus* but the common utility is not linked to a substantial structural feature. The products in this relationship are distinct if either or both of the following can be shown: (1) that the products encompass embodiments that are not required to perform the common utility or (2) that the products as claimed can be used to perform another utility. In this case, the antibodies could be used to purify the bacterium, in the passive vaccination of infected individuals or as a means of inhibiting growth on indwelling catheters.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case antigens can be used in a materially different method of use such as attached to a solid phase in an immunoassay to detect infection by assaying for antibodies that bind the antigen/polypeptide in the serum of patients.

Because these inventions are independent and distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, and in the absence of restriction would place an undue search and examination burden on the examiner,

restriction for examination purposes as indicated is proper. Because these inventions are distinct for the reasons given above and the inventions of the Groups I-IV require non-coextensive literature searches, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and

process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Mark Navarro can be reached on 571-272-0861.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy

Primary Examiner

AU 1645